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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,603	04/28/2006	William Suttle Peters	13634.4010	3360

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
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EXAMINER

PORTER, JR, GARY A

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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05/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,603	Applicant(s) PETERS, WILLIAM SUTTLE	
	Examiner GARY A. PORTER, JR	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding Claim 9, Applicant claims "a Luer-lock or similar gas tight fitting." It is unclear as to what types of fittings are encompassed by the term "similar". Given its broadest reasonable interpretation, the Examiner has treated this limitation as incorporating any type of gas-tight fitting or seal.

4. In regards to Claim 10, Applicant claims "the first and/or second gas line parts have a fluffy polyester, or similar, collar...." It is unclear as to what components are considered "similar" to a fluffy polyester collar. Given its broadest reasonable interpretation, the Examiner has treated this limitation as incorporating any type of collar made of a soft material, e.g. cloth.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Freed et al. (US Patent 6,132,363).

7. Regarding claim 1, the Examiner notes it has been held that the recitation that an element is "Adapted To" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Freed teaches a percutaneous gas-line for a medical device, the gas-line including a first gas-line part 28 capable of being wholly implanted, due to its size, in a patient and having a first end capable of sealing a connection to the medical device and a second end with a connection fitting (Fig. 1); and a second gas-line part 18 capable of being part-implanted and part-external and having a first (external) end capable of sealing a connection to an external driver (col. 4, lines 34-35) and a second (implanted) end capable of removably sealing a connection with the connection fitting 16 on the second end of the first gas-line part (Fig. 1,4; col. 4, lines 28-35; col. 9, lines 45-54). Furthermore, although Freed teaches the connection 12 between first 28 and second 18 gas line parts is partially external and partially internal (Fig. 3, 4), the Examiner notes the connection of the first gas line part 28 and second gas line part 18 is capable of being fully positioned within the body due to its size and is therefore "adapted" to be wholly implanted.

8. In regards to claim 2, Freed teaches the second gas-line part is further capable of being removed, for replacement, in the presence of persistent exit-site infection. This capability is shown by the detachable connection of the second gas-line part 18 to implanted connector 12 (Fig. 4)

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9. With regards to claim 3, Freed teaches the first (external) end of the second gas line is removably connected to the external driver (col. 4, lines 34-35).

10. In regards to Claim 4, Freed teaches an ECG lead 30 implanted in a patient's epicardium (col. 4, lines 20-27; col. 9, lines 45-54). Freed further discloses that ECG lead 30 is connected the drive unit 14 and that external line 18 is the only line connecting connector 16 to drive unit 14. As such, the ECG lead 30 must be incorporated into line 18 in order to establish connection with the drive unit (Fig. 3 and 5; col. 4, lines 20-26).

11. Regarding Claim 5, Freed discloses the gas line is small in diameter, i.e. 5 mm, is kink resistant (col. 4, lines 10-15), and is flexible (col. 4, lines 29-31).

12. In regards to Claim 9, the Examiner takes Official Notice that the connecting element 16 is gas tight since gas is being transferred from line 18 to line 28 through connector 16 in order to inflate bladder 10. The Examiner notes that if the connection were not gas-tight then the bladder would not inflate properly and unwanted gas would enter the body putting undue pressure on the internal organs, which would be counter to the desired operation of the system.

13. With regards to Claim 10, Freed teaches a cloth covered collar, i.e. flange at base 16 that covers a short section of internal gas line 28 (col. 14, lines 28-25; Fig. 5).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freed et al. (US Patent 6,132,363).

16. Regarding Claim 6, Freed discloses a gas line that is positionable within the human body in order to support a patient's cardiovascular function (Abstract). Freed also discloses that the internal gas line 28 has a diameter of 5 mm (col. 4, lines 16-20). Although Freed does not disclose the exact dimensions of the external line 18, one can ascertain that gas line 18 and 28 are of relatively the same diameter (Fig. 1 and 4). Given that the size of the second gas-line part 28 has a diameter close to that of the internal part, i.e. 5 mm, it would have been an obvious matter of design choice to alter the diameter of the second gas-line part to be 7 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

17. In regards to Claim 7, Freed discloses that the first gas line part 28 is wholly implanted and the second gas-line part 18 is capable of being implanted due to its dimensions and is connected to first gas-line part via connector 16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a biocompatible and biostable material for the construction of second gas line part 18, since it has been held to be within the general skill of a worker in the art to

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select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

18. In regards to Claim 8, Freed discloses all of the claimed invention except for the exact material composition of the gas line. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ silicone 45-65A durometer for the construction of second gas line part 18, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

19. Applicant's arguments filed 2/23/2009 have been fully considered but they are not persuasive.

20. Applicant argues at 7 of the Remarks that "it is clear from Freed's description that the 'second gas-line part 18' referred to by the Examiner is only external and not 'adapted to be part-implanted and part-external' as claimed." The Examiner respectfully disagrees. As noted in the action above, it has been held that the recitation that an element is "Adapted To" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Therefore, since the gas line part 18 of Freed is sufficiently small, it is capable of being external, planted or partially external and partially implanted.

21. Applicant further argues at page 7 of the Remarks that "the PAD connector 12 is clearly not 'positioned fully within the body of the patient in spaced relation with an exit

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site in the body of the patient through which the second gas-line part is adapted to pass' as claimed." The Examiner respectfully disagrees. The claim language recites "the connection... is adapted to be positioned fully within the body of the patient." As noted in the action above, it has been held that the recitation that an element is "Adapted To" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Therefore, due to the size of connector 12 and that it is already partially implanted, it is also capable of being fully implanted within the body.

22. In response to applicant's arguments at page 8 of the Remarks that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the ability of the gas-lines to be non-surgically reconfigured if the exit site becomes infected) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
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